Wake Forest Baptist Medical Center	Non-Waived Point of Care Testing (POCT) Quality Management Policy and Quality Control/Quality Assurance Procedures PRO-POCT-LAB-18	Type:	
		Effective Date:	03/1997
		Revised Date:	1/2021
		Contact:	Point of Care Testing Compliance
CLIA Laboratory Medical Director		Date Approved	
Signature: Signature on File			

1) General Procedure Statement:

To ensure quality Point of Care Testing (POCT) results, the Wake Forest Baptist Medical Center (WFBMC) Clinical Laboratory has developed a quality management (QM) plan for non-waived POCT. The POCT QM plan will follow WFBMC quality initiatives, as applicable.

To ensure compliance, the POCT program will follow manufacturer product instructions and all applicable federal, state and local regulations and the College of American Pathologists (CAP) governing standards. The most stringent standard of all regulatory authorities will be adopted as policy. Other standards pertaining to non-waived POCT will be addressed in separate policies or procedures and will be followed as stated in the regulatory standard. If a policy or procedure is required by a CAP standard pertaining to quality assurance or quality improvement, this document shall serve as such.

The Individualized Quality Control Plan (IQCP) and QM plan include quality control (QC), quality assurance (QA), and quality improvement (QI) activities. POCT QM procedures monitor indicators; such as accurate patient identification, correct specimen collection and handling, test result quality, appropriate quality control and IQCP procedures, and compliance with requirements for training and competency of testing personnel. The goal for these indicators is 100% compliance. QA reports are generated for user sites on an as needed basis. User sites are encouraged to report and discuss quality and safety issues related to POCT without fear of retribution.

A WFBMC multi-disciplinary POCT committee exists to address POCT issues, including but not limited to: regulatory concerns, quality issues, or requests for addition of new POCT service.

POCT QM procedures are reviewed biennially by the Clinical Laboratory POCT Medical Director. The POCT quality management plan is appraised annually for effectiveness and changes will be implemented as needed.

The POCT Compliance office staff have been given designee status as Technical Consultants by the Clinical Laboratory POCT Medical Director for review of POCT records.

a. Scope/Purpose:

This document establishes policies and guidelines for assuring quality of Point of Care Testing results and defines current quality management and improvement practices. Non-Waived POCT sites covered by the Clinical Laboratory CLIA and CAP certificates shall adhere to processes outlined in this document.

b. Responsible Department/Party/Parties:

i. Procedure owner: Point of Care Testing Compliance Manager

ii. Procedure: Non-Waived POCT sites covered by the Clinical Laboratory CLIA and CAP certificates shall adhere to processes outlined in this document.

iii. Supervision: The Medical Director for Point of Care Testing shall supervise the person(s) performing activities outlined in this document

iv. Implementation: Each applicable POCT site manager, preceptor, and/or POCT Compliance staff member is

responsible for ensuring compliance with processes stated in this document.

2) Definitions:

a. Point of Care Testing (POCT)—Tests designed to be used at or near the site where the patient is located, do not require permanent dedicated space, and are performed outside the physical facilities of the clinical laboratory.

b. Non-Waived Tests—Tests of moderate or high complexity as designated by the Food and Drug Administration (FDA).

c. Clinical Laboratory Improvement Amendments (CLIA)—United States federal regulatory standards that apply to all laboratory testing performed on humans.

d. Quality Control (QC)—Processes to ensure the test system is performing as expected.

i. Quality Control (QC) verifies the performance of the test system. (For example, analyzer performance, reagent/tube/cartridge performance, technique of testing personnel.)

ii. Controls are run daily for quantitative and qualitative tests. Follow device/reagent/manufacturer specific procedure(s) for details. Regulatory and accrediting agency requirements must be followed.

iii. QC results are to be evaluated for acceptability, prior to reporting patient results.

iv. There should be documentation of corrective action when control results exceed defined acceptability ranges.

v. Patient testing, using the affected equipment and reagents, MUST be discontinued until the problem is resolved and acceptable QC results are obtained.

vi. Control specimens must be tested in the same manner and by the same personnel as patient samples.

e. Quality Assurance (QA)—A system for ensuring a desired level of quality. The POCT program incorporates activities to monitor the quality of processes and the test system.

f. Quality Improvement (QI)—Activities implemented to improve the quality of processes.

g. Proficiency Testing (PT)—Unknown samples sent to a lab/test site by a Centers for Medicare and Medicaid Services (CMS)-approved PT program.

h. College of American Pathologists (CAP)—Accrediting agency for the WFBMC Clinical Laboratory. Point of Care sites included on the CLIA certificate of the Clinical Laboratory are accountable to standards set forth by CAP.

i. **Information Technology and Services (ITS)—**Medical center-wide department serving the clinical, research and academic enterprise.

j. Electronic Healthcare Record (EHR)--Digital version of a patient's paper medical chart.

k. Intellligent InSites (SPOT)—A WFBMC centralized temperature, humidity, and environmental continuous monitoring system.

l. ECRI—An organization that identifies and informs subscribers about health technology hazards and risks that could impact patient safety and quality of care.

m. **National Institute of Standards and Technology (NIST)** – A measurement standards laboratory and a non-regulatory agency of the United States Department of Commerce.

n. CAPA – Corrective Action/Preventative Action process for identifying, preventing and eliminating the cause of actual or potential nonconformity, using risk management principles.

3) QA Activities:

a. Daily:

i. Refer to method-specific procedures for daily quality related activities, such as performing quality control checks if applicable.

ii. Temperature and Humidity Monitoring:

- Temperature and humidity readings are checked and recorded at a minimum of once each day of use for all temperature-dependent reagents, equipment, and environments, using a NIST calibrated thermometer.
- If ambient temperature ranges are specified by the manufacturer, logs and records will be maintained to reflect these requirements. Corrective actions are taken when tolerance limits are exceeded. If actions taken cannot correct the problem, patient testing should cease until the problem is fixed.
- Monitoring may be achieved by using Minimum/Maximum thermometers/hygrometers or the WFBMC real-time SPOT tracking system.
    - If a NIST minimum/maximum thermometer is used to perform continuous monitoring of temperatures, both the low and high temperatures must be recorded and reviewed for acceptability.
    - The SPOT system sends email alerts to key individuals and the Service Response Center when readings fall outside of pre-defined limits of acceptability.
    - The Clinical Laboratory Point of Care Testing Compliance team reviews SPOT alerts and responds accordingly. Temperature alerts are rounded to the next whole number when evaluating an out-of-temperature event.
    - 86°F color change indicators are stored with small inventories of reagents in patient care areas. The lower temperature range is not monitored in patient care areas, due to the unlikeliness of temperatures reaching below the low temperature threshold.
    - In the event that the temperature or humidity exceeds manufacturer requirements, corrective and investigative actions will be taken and documented. Completion of the CAPA process for the main lab may be required.
- **Thermometric Standard Device**
    - An appropriate thermometric standard device of known accuracy (guaranteed by manufacturer to meet NIST Standards or traceable to NIST standards) is available and used when necessary.
    - Thermometric standard devices must be recalibrated, recertified, or replaced prior to the date of expiration of the guarantee of calibration, or they are subject to CAP requirements for non-certified thermometers.
    - Thermometers should be periodically evaluated for damage. Thermometers with obvious damage should be rechecked for continued use.
    - The Clinical Laboratory maintains NIST-verified thermometers. Annually, the NIST thermometers are checked for calibration by WFBMC Clinical Engineering and a verification statement is issued for the device.
    - The Medtronic HMS Plus heat block temperature is verified/adjusted monthly using a NIST calibrated Temperature Verification Cartridge and a calibrated thermometer, which is issued a certificate by the manufacturer. No expiration date is indicated.
    - **Non-certified Thermometers**
        - All non-certified thermometers in use are checked against an appropriate NIST thermometric standard device before initial use and as defined by laboratory policy.
        - If a digital or other display of temperature is used on equipment for daily monitoring, the laboratory must verify the accuracy of the read

out. The display must be checked initially according to manufacturer's instructions.

b. <u>Monthly:</u>

i. The Clinical Laboratory POCT Compliance office will perform monthly QC/QA review for the locations covered by the Clinical Laboratory CLIA certificate.

- Pre-analytical, analytical, and post-analytical variables will be included as part of the QA process to ensure result quality and safety. A performance report will be issued to the sites, as needed.
- Quality Control (QC) records will be reviewed and initialed each month by the Clinical Laboratory POCT Compliance` office. More frequent monitoring will occur as necessary. Site manager or site designee (Technical Consultant) is responsible for reviewing and signing QC records, prior to return to the Clinical Laboratory POCT Compliance office.

ii. <u>The following will be assessed, as applicable: (pre-analytical)</u>

- Verification that proper instrument identification is included on all QC and maintenance documents.
- Verification that QC has been performed each day of patient testing.
  - If a device was not used on a particular day for patient testing, it is acceptable to document "not in use" (NIU).
  - All NIU documentation should be initialed by staff member indicating the device was not used.
- Verification that all QC results are within acceptable limits and appropriate troubleshooting and follow-up action taken for QC outliers.
  - Assess whether further evaluation of the IQCP/risk assessment and quality control plan is needed based on problems identified.
- Verification that all required maintenance has been performed.
  - Instrument and equipment maintenance, function check, performance verification, and service/repair records will be promptly available to, and usable by, the technical staff operating the equipment.
- As applicable, Clinical Engineering repair reports will be reviewed.
  - QC reagents and testing reagents will be checked for expiration date.
  - Tubes/cartridges will be checked for QC validation, prior to patient use.
- If applicable, new lot numbers of QC material will be tested in the laboratory for range verification. For additional details, refer to document, “ACT Quality Control Range Verification as Performed by the Clinical Laboratory”.
  - If applicable, POCT reagent storage refrigerator temperature records will be reviewed.
- New employees who need training should be identified. It is the responsibility of the POCT user site manager to ensure that all users are trained and certified <u>prior to performing patient testing.</u> The POCT user site manager should forward up-to-date user lists to the Clinical Laboratory POCT Compliance office periodically.
- Non-compliance with above-stated items will be addressed on an individual basis and documented, as appropriate.
- **i-STAT Quality check (QC) codes and star out** rates will be monitored. **(analytical)**
  - QC codes should not exceed 5% each month
  - Star out rate should not exceed 2% each month.
  - Failures of these limits will be investigated by the Clinical Laboratory POCT Compliance office.

iii. **i-STAT Monthly Liquid QC:**

Liquid QC will be performed for each i-STAT test by various i-STAT user sites. Results should be within acceptable tolerance limits. QC will be rotated among different i-STAT users.

iv. **Quality Assurance Reports:**

As needed, QA reports are generated to monitor compliance rates of POCT user sites. In addition, the Wake Forest Baptist Health (WFBH) Patient Safety Net/RL6 is used, as needed. Incidents reported to this site include:

- ❖ i-STAT sample mis-identifications
- ❖ Non-compliance with QC policies and procedures
- ❖ Unauthorized use of POCT equipment
- ❖ Other incidents, as needed

- **Quality Indicators Reported to the Department of Pathology Quality Assurance Team:**
  - **Compliance with quality control (QC) procedures (pre-analytical)**
    - Expected Performance: 100% compliance
    - Unacceptable Threshold: <95%
  - **Sample Mis-identifications (pre-analytical/post-analytical):**
    - Expected Performance: Target is 0% misidentified samples
    - Unacceptable Threshold: >0.2%
  - **Proficiency Test Results (analytical):**
    - Expected Performance: Target is 100% of the PT values to be within acceptable tolerance limits.
    - Unacceptable Threshold: Less than 80% of the values within acceptable limits and/or subsequent failures of the same analyte across PT events.
  - **Unauthorized use/off-label use of POCT equipment or supplies (analytical)**
  - **Device-related adverse patient events (analytical)**
  - **Employee or clinical provider concerns related to test quality or safety (post-analytical)**
  - **Other, as needed**

c. <u>Biannual QA Activity:</u>

i. Comparison Testing

- As applicable to the methodology, POCT user sites which have duplicate analyzers should perform a sample comparison between analyzers to verify agreement at least twice per year.
- As appropriate, POCT analyzers are also compared against the Clinical Laboratory analyzers to verify agreement of test results.
- I-STAT and HemoCue 201+ methodology is compared against Blood Gas Lab methodology and Clinical Laboratory methodology, as appropriate.
  - The i-STAT Technical Bulletin, "Proficiency Testing on the i-STAT System" states, "All analyzers that pass the Electronic Simulator test are equivalent". Therefore, individual i-STAT handheld devices will not be compared against each other. The i-STAT methodology will be compared against appropriate Clinical Laboratory methods.
- AVOX analyzers are compared against one of the Blood Gas Lab co-oximeters.
- Activated Clotting Time (ACT) user sites, which have multiple analyzers, perform comparisons amongst analyzers to verify agreement of results.
- Calculated parameters are not compared.
- Quality control data may be used for comparison for tests performed on the same instrument methodology.
- **Comparison results should agree within acceptable limits – see below.**

Acceptable limits were established utilizing the CAP proficiency testing participant summary evaluation criteria as a guide and under the direction of the POCT Medical Director. Results should be forwarded to Clinical Laboratory POCT Compliance office for review.

- +/-10% for **ACT,** provided same method and clot activator is used
- +/- 1g/dL for THb and +/-3%HbO2 (**AVOX)**
- pH--0.04
- pCO2--5 mmHg or 8%, whichever is greater
- pO2--10% if analyzers are side-by-side during testing--+/-20% if testing not performed 'side-by-side'
- Potassium--0.5 mmol or meq/L
- Sodium--4 mmol or meq/L
- Ionized calcium--0.1 mmol/L
- Hemoglobin--1 g/dL
- Hematocrit--3%
- Creatinine--0.3 mg/dl or 15%, whichever is greater
- Lactate--20%
- INR--+/- 0.4 or +/- 20% if INR above 4
- Glucose--+/-6 mg/dl or 10%, whichever is greater
- Chloride--+/-5 %
- BUN--+/-2 mg/dl or 9%, whichever is greater
- Measured Total CO2--10%
- Other analytes may be added as necessary. Limits of acceptability will be established/approved by the POCT Medical Director at the time of implementation.

ii. Calibration/Calibration Verification

Calibration verification is the process of assaying reference standards or calibration materials in the same manner as patient samples to confirm that the calibration of the analyzer has remained stable throughout the laboratory's reportable range for patient test results.

- **ACT Calibration Verification:**

There are no calibration verification procedures for coagulation-based tests.

- **I-STAT Calibration Verification:**

Performed on the i-STAT analytes, with the exception of coagulation tests, each 6 months, using a manufacturer-approved calibration verification kit. The kit consists of 5 levels of test material that is tested in singlet. Manufacturer instructions are followed. Results should match insert values. Follow-up and corrective action is taken, as needed. Note: i-STAT cartridges are calibrated by the manufacturer. Calibration is 'controlled' by software upgrades issued by the manufacturer. Other on-site calibration options are not available.

- **AVOX Calibration Verification:**

Performed daily, weekly, and every 6 months. A linearity kit can also be used to verify calibration. Refer to AVOX procedure for details.

- **HemoCue 201+ Hemoglobin Calibration Verification:**

Performed on each new analyzer received and every 6 months (rotating analyzer used for testing) using a manufacturer recommended linearity/calibration verification kit. The kit consists of 5 levels of test material that is tested in duplicate. Manufacturer instructions are followed. Results should fall within the limits of acceptability included in the package insert of the calibration verification material. Follow-up and corrective action is taken, as needed.

iii. i-STAT Thermal Probe Check

- Thermal probes should be checked at least twice per year. Refer to the i-STAT System Manual for instructions.

iv. Analytical Measurement Range (AMR)

- Upper and lower limits of the AMR for all measured analytes are defined. Results falling outside of these limits are appropriately reviewed and retested, if necessary, before reporting. Manufacturer instructions are followed for validation of AMR.
    - **AVOX AMR**

    Validated every 6 months, as part of the calibration verification procedure.
    Manufacturer instructions are followed for validation of AMR.
    Results should fall within the limits of acceptability included in the package inserts of the calibration verification material.
    When new instruments are placed into service or following maintenance/repair, AMR will be validated.
    - **i-STAT AMR**

    Validated every 6 months, as part of the calibration verification procedure.
    Manufacturer instructions are followed for validation of AMR.
    Results should fall within the limits of acceptability included in the package inserts of the calibration verification material.
    When new instruments are placed into service, AMR will be validated.
    - **Coagulation Tests AMR**

    AMR validation is not necessary for coagulation tests.

d. <u>Annual QA Activities:</u>

- Annually, interfaced POCT result reports will be sent to the Medical Director for review and approval. The Medical Director will review and approve patient reports annually to verify content and format of the reports. Refer to the Laboratory General CAP checklist for additional requirements pertaining to patient report review.

e. <u>General Quality Assurance:</u>

i. Primary Specimen Container Labeling

- All primary specimen containers must be labeled with at least 2 patient-specific identifiers. Bare minimum is patient full name and date of birth. It is preferable to use a WFBMC patient identification label.

ii. Acceptability of New Reagents

- New test reagents will be checked for acceptability, prior to patient use, by performing liquid quality control checks. Confirmation will be made that patient reference and action ranges are not affected by the implementation of new test reagents.
- Liquid quality control values should be within acceptable limits, prior to patient use.
- QC values should read similar to the QC values obtained on the previous lot number of reagents to ensure that patient results are similar.
- Any reagent which fails liquid quality control checks should **not be used for patient testing, until a resolution is made.** If liquid QC checks fail after 2 repeats and no cause is identified, the manufacturer can be contacted for assistance.

iii. Reagent Labeling and Handling

- POCT sites will follow applicable manufacturer, regulatory, and Clinical Laboratory procedures related to reagent and product labeling.
- Reagents, calibrators, cellular controls, and solutions will be properly labeled, as applicable and appropriate, with the following elements:
    - Content and quantity
    - Concentration or titer
    - Storage requirements
    - Date prepared or reconstituted by the laboratory or POCT site

- Expiration date
- Other labeling, as required by regulatory authorities
- The laboratory must assign an expiration date to any reagents and media that do not have a manufacturer-provided expiration date. The assigned expiration date should be based on known stability, frequency of use, storage conditions, and risk of deterioration.

iv. Reagent Kit Components

- If there are multiple components of a reagent kit, POCT sites will use components of reagent kits only within the kit lot. In general, components of a kit should not be separated or mixed unless otherwise specified by the manufacturer.

v. Reagent Storage and Handling

- All reagents will be stored and handled according to manufacturer's instructions.
- Reagents will be stored and handled in a manner to prevent environmentally-induced alterations that could affect reagent stability and test performance. Prepared reagents will be properly stored, mixed when appropriate, and discarded when stability parameters are exceeded. If reagent preparation results in a change of expiration date, the modified expiration date must be written on the label.
- If the manufacturer defines a required storage temperature range, the temperature of storage areas must be monitored daily to ensure proper performance.
- If a problem is identified with a reagent that was used for patient testing, such as an expired reagent or reagent subjected to unacceptable storage condition, impact on patient results will be evaluated in conjunction with the medical director of the point of care testing section. Records of the evaluation and actions taken will be maintained.

vi. Installation/Validation of New Methodology

- The Clinical Laboratory Medical Director for POCT will approve all new POCT methods/equipment, prior to live patient testing. In addition, the Clinical Laboratory Medical Director for Point of Care Testing will review validation procedures for each new non-waived installation. The Medical Director's signature on validation records/reports indicates approval of the test device for patient use, unless additional verbiage indicates otherwise.
- For methods implemented after June 15, 2009, the method validation should include:
    - A written assessment of each component of the validation or verification study, including the acceptability of the data.
    - If data includes discordant results, there must be a record of the discordance and investigation of any impact on the approval of the test for clinical use.
    - An approval summary statement, signed by the laboratory director (or designee who meets CLIA director qualifications), documenting review of validation studies and approval of each test for clinical use.
- The summary statement must include a written assessment of the validation/verification study, including acceptability of the data and approval for clinical use for each non-waived test.
    - An example of such a statement is: "I have reviewed the verification/validation data for accuracy, precision, reportable range, interfering substances, and reference range studies and performance of the method is considered acceptable for patient testing."
- If multiple identical instruments or devices are in use, there must be records showing that the method performance specifications have been separately verified for each test and instrument/device. The evaluation and data must clearly support the decision to approve the test for clinical use.
- For FDA-cleared/approved tests, a summary of the verification data must address analytic performance specification, including analytic accuracy, precision, interferences, and reportable range, as applicable.
- Prior to implementation of new POCT methods, precision, accuracy, linearity, reportable range, reference range and interfering substances may be validated/investigated by the following methods, as applicable:
    - Repeat testing of 2 levels of liquid quality control material.

- ❖ Mean, standard deviation and coefficient of variation should be calculated and should agree with manufacturer's claims.
- Patient comparison samples will be tested against current in-house methodology.
- Manufacturer information may be used to evaluate precision, accuracy, reportable range, reference range, linearity, sensitivity and interfering substances.

- Refer to ***Method Validation Process Non-Waived Testing*** for additional information (POC Global Policies and Procedures Manual).

vii. Method Performance Specifications Availability

The laboratory's current test methods, including performance specifications and supporting validation data (analytic accuracy, precision, analytic sensitivity, test method interferences, reference range, and reportable range, as applicable), are available to clients of the laboratory and to regulatory inspection teams upon request. Supporting data will be made available for clinical performance claims, if applicable, validated or verified by the laboratory or obtained from peer-reviewed literature. The laboratory will also provide data on clinical validity, if available, to clients upon request.

viii. Analytic Methodology Changes

If the laboratory/point of care test site changes its analytic methodology so that test results or their interpretations may be SIGNIFICANTLY different, the change is explained to clients.

ix. Individualized Quality Control Plan (IQCP)

- Under certain circumstances, daily controls may be limited to electronic/procedural/built-in controls, provided appropriate validation studies are performed and an IQCP is established in conjunction with a risk assessment for the test method. Refer to current CAP POCT/Lab General/All Common checklists for additional details.
- External control material samples must be analyzed at least every 31 days and with new lots and shipments of reagents or more frequently if indicated in the manufacturer's instructions.
- All POC tests using an IQCP will be identified and appropriate CAP forms will be completed per CAP instructions and reviewed annually, unless the need arises to further evaluate the risk assessment and quality control plan based on problems identified.
- The Quality Control Plan will include the following elements:
  - The number, type (external and internal quality control systems), and frequency of quality control.
  - Criteria for acceptable performance
  - Monitoring of the testing environment and reagents
  - Specimen quality
  - Instrument calibration, maintenance, and function checks
  - Training and competency of testing personnel
  - Provisions for multiple identical devices and variation for uses covered under one IQCP
- WFBH uses IQCP E-Optimizer by Cola Resources, Inc. (CRI) to assess the seven components of the QC Plan listed above.

x. Analyzer Validation Post-Repair

- To verify performance, analyzers which are returned from manufacturer or Clinical Engineering repair, should have acceptable/applicable electronic and acceptable/applicable liquid quality control performed. Verification should be completed prior to release of the device for patient use. Prior to patient use, i-STAT analyzers should have appropriate programming entered into the analyzer, as noted below.
  - **i-STAT**
    - Verify the current date, time, JAMS, and CLEW are programmed into the analyzer.
    - Appropriate WFBMC configuration should also be programmed, via the I-STAT data management system.
    - Unit should be set to the appropriate resulting panel.
    - The electronic simulator should be tested and should pass successfully.
    - The barometric pressure (BP) should be verified against the ICU Blood Gas Lab barometer. The i-STAT BP should compare with the barometer +/- 6 mmHg.
    - The thermal probe check should be completed. Refer to I-STAT System Manual for instructions.

xi. Detection of erroneous, spurious, or unusual laboratory results

- There is a documented system in operation to detect and correct significant clerical and analytical errors, and unusual laboratory results, in a timely manner.
  - Examples of such processes include, but are not limited to:
    - Daily i-STAT critical value report
    - Medtronic HMS Plus data manager review
    - Random patient chart audits, included as part of annual competency
    - Each POCT procedure lists common situations that may cause analytically inaccurate results, together with instructions for how to address such situations.

xii. Correction of Clerical Errors/Erroneously Reported Results/Lab Records

- Changes must be legible and indelible.
- When an error is detected in reported lab records, the following should occur:
  - **Patient Result Reports**
    - Immediately notify providers of affected patients.
    - If results are already posted in the electronic health record, it is imperative that incorrect results be corrected immediately.
    - The testing staff member is responsible for correcting the electronic health record and all associated documentation. Ensure that result printouts or other documentation in the user site are corrected.
    - All corrections should always include the following information:
      - Full name and credentials of provider that was notified
      - Date of notification
      - Time of notification
      - Name of person that notified the provider
      - Reason/explanation for correction
    - File an RL6 Report.
    - Request credit for POC tests by contacting Lab Billing.
    - All corrected reports of previously reported, incorrect patient results are identified as corrected, and both the corrected and original data are clearly identified as such. The original data will be present in the corrected report or linked electronically to the corrected information.
    - If multiple corrections exist, all corrections should be referenced in sequential order on subsequent reports. All corrections should be referenced in the patient report.
  - **Lab Maintenance or Quality Control/Assurance Records**
    - Original (erroneous) entries must be visible or accessible
    - Erasures, white and correction fluids are unacceptable.
    - Corrected data, including the identity of the person changing the record and when the record was changed, must be accessible to audit.

xiii. Product Recall

- If a product recall occurs, which is related to currently used POCT equipment or reagents, the Clinical Laboratory POCT Medical Director will be notified and will determine an appropriate action plan.
- All actions will be appropriately documented. The ECRI Alert system will be used to document actions taken.
- Whenever patient results have been reported using the recalled product, as appropriate, the ordering physician will be notified about the recall specifics. POCT Medical Director instructions will be followed, regarding physician notification.

xiv. Device Related Adverse Patient Events

- In the event of an adverse patient event related to POCT equipment, the incident will be reported to the site manager, patient physician, POCT Office, Clinical Laboratory POCT Medical Director, WFBMC Risk Management, the device manufacturer and FDA, as applicable.
- All actions will be coordinated with the Clinical Laboratory POCT Medical Director.

xv. Critical Equipment Incidents

- Critical equipment incidents will be reported in the POC monthly QA reports. This includes any incident involving an instrument that could cause problems or delays in patient care. These could be from the instrument itself or from user error.

xvi. Employee Concerns Regarding Test Quality and Safety

- Should employees have concerns regarding POCT result quality or safety, the concerns should be reported to the site manager, Clinical POCT office, Clinical Laboratory POCT Medical Director, or the WFMBC Patient Safety Net/RL6. Concerns, which are not adequately addressed, can be confidentially reported by the employee to the College of American Pathologists (CAP) at 1-866-236-7212.

xvii. Employee and Physician Satisfaction

- All suggestions from within or outside the Department of Pathology for additions or improvement in the services offered will be reviewed. Requests for adding point of care testing service must be submitted to the WFBH POCT Committee. Complaints, problems, and issues communicated to the Clinical Laboratory POCT office will be reported in the monthly POCT QA report(s), along with a summary of follow-up action taken.

xviii. Point of Care Testing Interface Downtime

- If the POCT interface or data management systems become temporarily non-functional, appropriate measures will be taken to ensure that results are posted to the electronic health record (EHR).
- Patient treatment and care would not be affected by such a downtime.
- Patient care staff members have immediate access to the results on the handheld analyzer. POCT analyzers retain results in memory.
- During an extended downtime, I-STAT handheld analyzers may be swapped to avoid loss of data to the EHR. When interface communications are restored, the data will be downloaded to the EHR.
- Hardware is monitored by ITS for performance.
- The system will alarm in the event of a server failure.

xix. i-STAT Data Management System Back-Up

The i-STAT data management system is backed up nightly to the WFBMC ITS network.

xx.i-STAT Data Management Support

If support is needed (including after hours, weekends, and holidays):

1- Contact the WFBMC Help Desk (6-HELP)
2- Contact i-STAT Tech Support (1-800-366-8020)
3- Contact Abbott Tech Support (1-877-529-7185)

xxi. Proficiency Testing

Proficiency General Information

Non-waived POCT that is not considered a primary test method and is also covered by the same CLIA certificate as the Main Clinical Laboratory, CLIA ID 34D0664386, may not subscribe to a proficiency testing program. However, this testing does participate in biannual comparison testing with the clinical laboratory to verify performance of the test method. Sites not included on CLIA ID 34D0664386 and that do not have a primary method that reports the same analyte(s) as the POC method must participate in a CMS-approved proficiency testing program.

Proficiency Instructions

- Instructions provided with the proficiency survey samples will be followed, including but not limited to sample handling, analysis, and result reporting.
- Current accrediting and regulatory standards are followed.
- Testing is completed by POC testing personnel who routinely test patient samples, using the same primary method system as is used for patient sample testing. Results are returned to the Clinical Laboratory POCT office for submission to CAP for evaluation.
- The proficiency samples are rotated among different users.

Proficiency Sample Handling

- All PT samples in the kit should be tested on the Same Day.
- One staff member should test All samples that come in the survey kit (referenced as PT event).

- Testing of PT events should be rotated among testing personnel each calendar year, as available.
- A goal, but Not a requirement, is to follow this rule, At least one PT event-- per year-- per staff member when possible. Managers will keep track of personnel testing PT to make sure that one person is not always performing the PT.
- One analyzer should be used to test All samples that come in a survey kit (referenced as PT event).
- A PT event should be handled the same as a patient sample, so analyzer selection should be as if it were a patient sample in the workflow. The analyzer used for proficiency testing is not assigned. The analyzer used is at the discretion of the testing staff member, when this is the workflow for patient samples.

Proficiency Communication

- **The following communications, regarding specific result values, are prohibited until after the proficiency provider submission deadline.**
  - Communication between the Clinical Laboratory and POCT sites
  - Inter-laboratory communication
  - Inter-POCT site communication
- Proficiency testing records must not be shared with and should not be accessible to personnel of other laboratories, including an affiliated laboratory, until after the deadline for submission of results.
- If a common computer system houses proficiency results, appropriate steps are taken to ensure that records are not readily accessible by other laboratories.

Proficiency Sample Referral

- It is strictly forbidden to refer or accept proficiency testing samples from any site other than the specified POCT site.

Proficiency Result Review

- The attestation statement will be signed by the Laboratory Director or qualified designee and all individuals involved in the testing process.
- Physical signatures must appear on a paper version of the attestation form. A listing of typed names on the attestation statement is not acceptable documentation.
- The Clinical Laboratory POCT Compliance office and Clinical Laboratory POCT Medical Director will review all proficiency results.
- Proficiency results will also be evaluated for bias or trending. Any follow-up action taken will be documented on the CAP result report.

Proficiency Failures

- If proficiency results fail, or Lab does not submit results, the problem is investigated and resolved as necessary.
- Failed proficiency testing results will be evaluated for appropriate resolution action and documentation noted.
- Investigation into proficiency failures will include review of quality control performed for that day and for the reagents used in proficiency testing.
- Instrument performance will be evaluated.
- Testing personnel training and competency assessment will be verified. Re-training will occur, as needed.
- Proficiency sample handling will be investigated as a possible cause of the failure.
- All investigative, follow-up, and corrective actions will be documented.
- The Clinical Laboratory POCT Medical Director will review proficiency result failures and investigation documentation.

Non-Evaluated Proficiency Results

- If proficiency results were not evaluated by CAP due to lack of consensus, the results were submitted after the cut-off date, or the results were reported incorrectly to CAP, they will be compared against the results published by CAP included with the CAP report.

- This will verify acceptable proficiency performance by point of care testing sites.
- Failures will be investigated and documented, as noted above.

Proficiency Record Retention

- Primary records related to PT and alternative assessment testing will be retained for two years (unless a longer retention period is required elsewhere in other regulations).
- This includes all instrument tapes, work cards, computer printouts, evaluation reports, evidence of review, and documentation of follow-up/corrective action.

Proficiency Testing for Analytes not Covered by CAP Proficiency Testing

- For tests for which CAP does not require PT, the laboratory will at least semi-annually exercise an alternative performance assessment system for determining the reliability of analytic testing.
- An acceptable program will be established at the direction of the Clinical Laboratory POCT Medical Director.
- There is no communication regarding proficiency results between the Clinical Laboratory and test sites until after proficiency testing is completed and evaluated.
- Failed proficiency testing will be evaluated for appropriate resolution action and documentation noted on the records. The Clinical Laboratory POCT Medical Director will review proficiency failures.

xxii. Intermittent Testing

- Tests are considered to be taken out of production when (1) patient testing is not offered AND (2) PT or alternative assessment, as applicable, is suspended.
- When a test is put back into production, the following requirements must be met:
  - PT or alternative assessment performed within 30 days prior to restarting patient testing
  - Method performance specifications verified, as applicable, within 30 days prior to restarting patient testing
  - Competency assessed for analysts within 12 months prior to restarting patient testing.

xxiii. Document Control Policies/Procedures/Guidelines

- All current POCT policies/procedures/guidelines for use of equipment will be made available to each POCT user site. These documents are posted on the WFBMC Intranet Point of Care Testing web site. Each staff member is trained in how to access electronic POCT documents.
- Content will be compliant with CAP standards for required elements of procedures. Refer to CAP standards for details.
- A listing of current POCT policies/procedures/guidelines can be found in Title 21 and Policy Tech Document Control management systems and on the POCT website on the intranet.
- Documentation of review by POCT users will be included as part of the initial training process. It will also be included as part of the yearly competency evaluation process.
- The Laboratory CLIA Director and Clinical Laboratory POCT Medical Director will approve all POCT policies/procedures/guidelines and major modifications to POCT policies/ procedures/guidelines prior to implementation in POC test sites.
- All POCT policies/procedures/guidelines will be reviewed and signed biennially by the Clinical Laboratory POCT Medical Director.
- Discontinued policies/procedures/guidelines will be kept for a minimum of 2 years following discontinuance. Initial date of use and retirement date (out of use date) will be recorded.

xxiv. Record Retention

- The following records must be retained for at least 2 years:
  - Specimen requisitions (including the patient chart or medical record only if used as the requisition)
  - Patient test results and reports, including original and corrected reports
  - Instrument printouts and worksheets
  - Accession records

        - Quality control records
        - Instrument maintenance and function checks records
        - Proficiency testing records
        - Quality management records
        - Manual computer entry of patient result data from worksheets, print-outs, etc.
        - For results that are manually entered into the computer from 1) observation of an electronic display, with no paper print-out available or 2) manually performed test methods without worksheets, the two-year retention requirement applies to the data within the computer.
        - Ongoing computer system checks (e.g. calculation verification)
        - Training records
        - Competency assessment records
        - On-going quality assessment data
    - Instrument maintenance records may be retained for longer than the 2 year requirement (e.g. for the life of the instrument), to facilitate troubleshooting.
    - Individualized Quality Control Plans (IQCP), including risk assessment and supporting data, and approval of the quality control plan must be maintained 2 years following discontinuation of the IQCP.
    - Records of method performance specifications must be retained while the method is in use, and for at least two years afterwards.
    - For data directly transmitted from instruments to the laboratory computer system, via an interface (on-line system), it is not necessary to retain paper worksheets, printouts, etc., as long as the computer retains the data for at least two years.
    - For requirements on retaining records of changes to software, the test library, and major functions of laboratory information systems, please refer to the Hardware and Software section of the Laboratory Computer Services section of the CAP Lab General Checklist.
    - In the event the laboratory ceases operation, all records will be retained and available for the appropriate times.
    - Current and applicable regulatory or accrediting agency standards will be met.

xxv. Specimen Retention

- Specimens of serum, heparinized plasma, EDTA plasma, CSF, and body fluids (except urine) should be retained for 48 hours. The 48 hour retention requirement does not apply to whole blood samples; for example, samples collected for blood gas or activated clotting time (ACT) testing.
- Urine specimens should be retained for 24 hours; exceptions may be made at the discretion of the laboratory director.
- Blood films, permanently stained body fluid slides, and permanently stained microbiology slides prepared from clinical specimens (including blood culture bottles) should be retained for 7 days.
- Specimens must be kept under appropriate storage conditions.

xxvi. Health Insurance Portability and Accountability Act (HIPAA)

- The WFBMC POCT program will follow HIPAA regulations and requirements to protect patient confidentiality.
- Appropriate measures will be taken to avoid disclosure of protected health information to unauthorized personnel.
- In regards to HIPAA, the POCT program will follow policies and procedures established by WFBMC.
- Patient data is accessible in a timely manner only to those individuals who are authorized to review test results.
- NOTE: Only those healthcare personnel authorized to review a patient's test results should have access to those results. Laboratories subject to US regulations must provide final test results to the patient or the patient's personal representative upon request. For completed tests, these results must generally be provided no later than 30 days after such a request.

- Under the HIPAA Privacy Rule, only the patient or a personal representative, defined as an individual who has authority under applicable law to make health care decisions for the patient, can be given access to a patient's personal health data. Laboratories must take reasonable steps to verify the identity of the patient and the authority of a personal representative to have access to an individual's protected health information. The Rule also allows for the release of test reports to authorized persons responsible for using the test reports and to the laboratory that initially requested the test, if applicable.
    - **i-STAT HIPAA Protective Measures**
        - Access to i-STAT results is protected by user ID. Only staff members trained in use of i-STAT can access i-STAT handheld results.
        - Whenever an i-STAT user is terminated or no longer uses the i-STAT test device, the user site supervisor should notify the POCT office. A staff member from POCT Compliance will remove testing access from applicable i-STAT data management systems.
        - Access to the i-STAT data manager is password protected and electronically documented.
        - Access for any individual is specifically programmed into the system by a staff member from POCT Compliance office.
        - The i-STAT data management system can be viewed for a current list of users who have access.
    - **Medtronic HMS Plus HIPAA Protective Measures**
        - Access to Medtronic device is protected by user ID. Only staff members trained in use of this device can perform testing.
        - Whenever a Medtronic HMS Plus user is terminated or no longer uses the device for patient testing, the user site supervisor should notify the POCT office and delete the user's access from the test device user database.
        - It is the responsibility of the user site manager and/or POCT user site coordinator to ensure accurate operator database information.
    - **Other POCT Equipment with Operator ID and Patient ID Entry HIPAA Protective Measures**
        - **Should any new POCT equipment be purchased or added to the Clinical Laboratory POCT menu, WFBMC and ITS policies will be followed to ensure patient confidentiality.**
    - **Analyzers Returned to Manufacturer for Repair HIPAA Protective Measures**

      Any analyzer/system that is sent outside the WFBMC facility will have the database cleared if patient information is included in the database. In the event that patient data cannot be cleared prior to return to the manufacturer, the manufacturer must have a signed a Business Associate agreement on record with WFBMC to address HIPAA concerns.

xxvii. Patient Reports

An individual meeting CAP laboratory director qualifications reviews and approves the content and format of paper and electronic patient reports at least every two years, whether paper or computer screen images, to ensure that they effectively communicate patient test results, and that they meet the needs of the medical staff.

- The paper or electronic report must include the following components:
    - Name and address of testing laboratory
    - Patient name and identification number, or unique patient identifier
    - Name of physician of record, or legally authorized person ordering test, as appropriate
    - Date of specimen collection, and if appropriate, time of collection
    - Testing personnel's name
    - Date of release of report (if not on the report, this information should be readily available)
    - Time of release of report, if applicable (if not on the report, this information should be readily accessible)
    - Specimen source, when applicable

- Test result(s) and units of measurement, when applicable
- Conditions of specimen that may limit adequacy of testing
- Reference intervals, as applicable
    - All patient results will be reported with reference (normal) intervals/ranges or interpretations, as appropriate. Reference intervals/ranges will not be reported when the test result is part of a treatment protocol that includes clinical actions, which are based on the test result.

xxviii. Critical Values

- Critical results are test results that fall outside high and low critical limits, which define the boundaries of life-threatening values for a test.
- Critical results represent an emergency condition and should be reported immediately to the patient's attending physician, nurse, or mid-level provider.
    - **Verbal Critical Result and Verbal Orders "Read Back"**
        - All POCT sites should follow the WFBMC policy for "read back" of critical results and verbal orders.
        - The policy "Calling Critical and/or Corrected Values" should be followed regarding read back of verbally reported critical values.
        - Anytime an order or critical result is verbally reported, re-back should occur to ensure accuracy of results. Documentation of read-back should occur.
    - **Documentation of Critical Result Notification**
        - All critical results reported by point of care testing devices that do not routinely get reported/notified immediately to an authorized clinical provider—physician, nurse, or mid-level provider—must be reported/notified within 15 minutes of result availability. Documentation of notification should occur.
        - Documentation of notification should be noted in the patient record.
        - Documentation should include:
            - Notifying individual's initials/signature
            - The critical result
            - Notifying Date
            - Notifying Time
            - Name and credentials of the person who is notified of the critical value
        - The author's name should be legible and authenticated.
        - Documentation pertaining to the person that is notified of the critical value should be identifiable for future questions.
        - At a minimum, last name and credentials should be documented. It is preferred that the full name of the provider be documented.
        - Critical values should be properly evaluated with the patient's clinical symptoms and followed up with necessary laboratory confirmation.
        - Any unexpected result should be repeated or sent to the clinical laboratory for confirmation.
    - **Critical Value Notification Quality Assurance**

      Compliance is monitored by POC test sites.
        - Audit of patient testing is performed for each POCT staff member, as part of annual competency assessment.
        - The audit is performed to ensure critical values are notified and documented within the defined critical value notification threshold.
        - Expected performance is 100% compliance.

xxix. Interface Result Integrity

- At least annually, results are verified to ensure they accurately transmit from the point of data entry (interfaced instruments and manual input) to patient reports (whether paper or electronic).
    - This is achieved by patient chart audit completed as part of competency assessment or during Wake One integrated testing, as applicable.
- In addition, verification is performed prior to implementation of a new interface, and every 2 years thereafter.
    - This includes evaluation of data transmitted from the POC devices to the electronic health record.
    - Reference ranges and comments, as well as actual patient results and report formats, are evaluated.
    - Interface validation will include examples of individual results, test packages or batteries, abnormal flags, and results with comments. Initial interface validation will include verification that corrected results for clinical laboratory results are handled accurately in the receiving system.
- Verification of accurate data transmission from the POC interface to other systems is performed by reviewing data in the first downstream (or interfaced) system in which the ordering clinician may be expected to routinely access patient data (Lab tab of Wake One). This requirement is met by printing screen shots or patient reports that document that a verification procedure has been performed.

xxx. Personnel

- **Analyst Tracking ID:** There is a system which tracks the identity of the testing staff member. The test date/time can be established. This is accomplished by electronic tracking or use of name/signature noted with POC results.
- **Job Description:** All staff members that perform POCT must have a job description statement that outlines POC accountabilities. For example, *"Performs and maintains competency for point of care testing as assigned, ensuring compliance with WFBH policies and applicable state and federal regulations."*
- **Employee Training and Competency Assessment:** Current regulatory standards will be followed.
    - A copy of diploma or transcript must be on file for each staff member that performs non-waived point of care testing. Staff members will not be allowed to perform POC testing until education documentation is confirmed.
    - Individuals that have received all of their education outside of the United States must have documented education equivalency in their personnel file.
    - Records will be maintained, documenting that all staff have satisfactorily completed initial training on all instruments/methods applicable to their designated job. The records will show that training specifically applies to the testing performed by each individual.
    - Training documentation, regarding specimen collection techniques will be maintained.
    - Retraining and reassessment of competency must occur when problems are identified with employee performance.
    - Testing personnel are required to score at least 80% correct on written competency assessment and must be deemed 'competent and can perform independently' on the competency observation.
    - Competency may only be assessed by an authorized individual meeting the qualifications of Technical Consultant, as defined by CLIA 42 CFR §493.1411.
    - **Competency will be assessed at the following intervals:**
        - Following training and before the staff member performs patient testing
        - During the first year of an individual's duties, competency must be assessed at least semiannually.
        - After an individual has performed his/her duties for one year, competency must be assessed annually.
    - **Elements of 6 Month and Annual Competency:**
        - Direct observation of routine patient test performance, including, as applicable, patient identification and preparation and specimen collection, handling, processing and testing

- Monitoring the recording and reporting of test results, including, as applicable, reporting critical results
- Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records
- Direct observation of performance of instrument maintenance and function checks, as applicable
- Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples
- Evaluation of problem-solving skills

- **Competency Corrective Action:**

Any user that fails to meet the competency requirements will need to be re-educated for use of the system. A documented remediation process shall occur.

- Reeducation of the staff member by an authorized individual
- Review of applicable policies and procedures by the staff member
- Observation of testing by an authorized staff member meeting CLIA technical consultant qualifications.
- Retake of written exam with a score of at least 80% correct.

- The Clinical Laboratory POCT Compliance office and user site manager maintain training and competency records.

xxxi. Patient Chart Audit

- As a component of annual competency, patient records will be audited to verify proper documentation of patient results.
- Audit will confirm the result, date, time, units of measure, critical value notification, if applicable, and documentation of the person performing the test.
- A clear audit trail should be established to determine testing personnel, reagents and analyzer used for testing.
- An audit confirming documented physician order for the test will also be completed.
- If documentation is not complete, the user site manager/designee should counsel the employee. Follow-up action will be taken as necessary. For example, credit of testing that has no documented provider order or follow-up action for notification/documentation of a critical value.

xxxii. Arterial Punctures

- Personnel performing arterial punctures should be knowledgeable about the more significant complications of this procedure compared with a venipuncture.
- The Department of Respiratory Care is responsible for maintaining training/education/competency documentation for staff members that collect blood gas specimens.
- If staff members from other disciplines perform arterial punctures, the applicable department is responsible for maintaining records of training/education/competency.

xxxiii. Blood Gas Testing

--Test for Collateral Circulation

- For radial artery sampling, a test for collateral circulation is performed and documented before arterial puncture, as applicable.
- The site from where the sample was obtained should be documented.
- Clinical sites performing radial artery punctures are responsible for defining situations that require testing for collateral circulation. Preferred technique should be identified.
- **Documentation of Test for Collateral Circulation (Allen's Test) Monitoring**
  - Respiratory Care will complete a random chart audit of at least 10 patient records to document compliance with performance/documentation of the Allen's Test at least biannually.
  - The report will be provided to the Clinical Laboratory POCT Compliance office for review.

--**Ambient Air Contamination**

- A system will be in place to prevent ambient air contamination.

- All specimens collected for blood gas analysis should be free of air contamination and capped immediately after sample collection.
- At the time of collection and at the time of testing, samples should be handled in a manner to avoid air contamination.

xxxiv. Safety

- Follow all WFBMC Infection Control policies and procedures.
  - **Standard Precautions**—Hand Hygiene
    Standard precautions are used for point of care testing by testing personnel. Gloves must be worn during testing events, hand hygiene performed, and gloves changed between each patient contact, according to Standard Precautions.
  - **Single-Use Capillary Stick Devices**
    - Only auto-disabling single-use capillary stick devices will be used for collection of blood samples for point of care testing.
    - Single-use devices should only be used for one patient.
  - **Disinfection of POCT Test Devices/Analyzers**
    - All POCT analyzers should be disinfected between each patient use.
    - Follow all manufacturer guidelines.

4) Review/Revision/Implementation:

a. Review Cycle: Each 2 years

i. All new policies/procedures/guidelines and those that have major revisions must be reviewed/signed by the CLIA Laboratory Medical Director.

ii. Review/sign-off can be completed by the designated section Medical Director in the following circumstances:

- Biennial review
- Minor document revisions

b. Office of Record: Point of Care Testing Compliance

5) Related Policies/Procedures/Guidelines:

a. Point of Care Testing Using the i-STAT Analyzer System PRO-POCT-LAB-09
b. Quality Control (QC) Range Verification PRO-POCT-LAB-19
c. Oxyhemoglobin and Total Hemoglobin Measurement Using the AVOXimeter 1000E Analyzer PRO-POCT-LAB-21
d. Medtronic HMS Plus Hemostasis Management System Version 4.0 PRO-POCT-LAB-23
e. Quality Assurance Plan Point of Care Testing PLAN-POCT-LAB-101
f. Documentation of Foreign Equivalency for Laboratory Testing Personnel Lab Admin 3
g. Competency Assessment for Non-Waived Testing
h. Proficiency Testing Procedure Lab Admin 12

6) References:

a. College of American Pathologists (CAP) Lab Accreditation Program Lab General, All Common, and Point of Care Testing checklists, CAP, 325 Waukegan Rd, Northfield, Illinois 60093-2750, Revised 6/04/2020

7) Attachments:

Other Associated Forms and Documents

- Bi-Annual Comparison Testing
  - I-STAT, HemoCue 201+, Blood Gas Lab, Core Lab Instruction Form
  - ACT-ECMO
  - ACT-EP Lab
  - ACT-Interventional Radiology
  - ACT-Cath Lab
  - ACT-Perfusion

- ACT-OR Blood Gas Lab
- AVOX 1000E 6-Month Analyzer Comparison Form (refer to AVOX 1000E Procedure)

▪ Bi-Annual iSTAT Calibration Verification Statement Template

8) Revised/Reviewed Dates:

Document Adopted: 3/97

Revised:

10/99
04/22/01
06/20/02
01/23/03
10/22/03
06/09/04
05/06
3/08
07/09
5/2010
11/2010
8/2011 (renamed using WFBMC rather than NCBH)
2/2013
10/2014 (renumbered to PRO-POCT-LAB-18)
2/2017

Review Date	Revision(s)	Signature
2/7/2019	2/7/2019 • Contact/Proc Owner/Office of Record changed to Clinical Laboratory Compliance Point of Care • Delete DHP Phlebotomy i-STAT users from sites that will adhere to processes outlined • QA Activities (Monthly ii. under Verification that all QC results are within acceptable limits and follow up action taken) add a bullet - Assess whether further evaluation of risk assessment and QC plan is needed based on problems identified • Under Proficiency Testing – delete CAP quality cross-check samples information • References – update revision date for CAP checklists	

3/2019	3/2019 Added NIST and CAPA information; Added reference to Method Validation Process Non-Waived Testing; Added- IQCP reviewed annually unless further evaluation of IQCP/risk assessment and QC plan is needed based on problems identified (p9); Added WFBH uses IQCP E-Optimizer by CRI to assess the 7 components of the QC Plan (p9); Added- including after hours, weekends, and holidays to i-STAT Data Mgmt Support (p11); Added- Testing Staff Name to patient report requirements (p16)	
7/2019	Added general Calibration Verification information and specific information for HemoCue 201; revised attached form Bi-annual Comparison Testing – ACT Perfusion	

01/2021